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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,201	04/12/2000	Georg Breier	VOSSI110	9638

7590 04/23/2002
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EXAMINER

PAPPU, SITA S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/23/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/445,201	BREIER ET AL.	
	Examiner	Art Unit	
	Sita Pappu	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 25-33 and 36-44 is/are pending in the application.
- 4a) Of the above claim(s) 12, 15, 16, 25-33 and 36-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 14, 17-23 and 42-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-23, 25-33, 36-44 are pending in the instant application. This Office Action is in response to the Amendment C filed by the Applicant in paper # 22 on 02/12/2002.

Response to the amendment

It is noted that new claims 41-43 are added by the Amendment C; however, since claim 41 was already introduced by the amendment A in paper # 9 filed 12/02/1999, the instant new claims have been renumbered as 42-44, as per 37 C.F.R. 1.126. Currently, claims 1-11, 13, 14, 17-23, 42-44 are under consideration.

Objection to the Figure 1 is withdrawn in view of the amendment made to the specification on page 29, third paragraph, which describes the Figure 1.

All rejections of claims 24, 34 and 35 have been rendered moot in light of cancellation of these claims (paper # 22, filed 02/12/2002).

The rejections of claims 1-11, 13,14, 17-23 under 35 U.S.C. second paragraph have been withdrawn in light of amendments filed 02/12/2002.

The rejection of claims 20-23 under 35 U.S.C. 112, first paragraph, for lack of enablement has been withdrawn in light of Applicant's amendment and arguments.

The rejection of claims 1- 7, 9, 10, 13,14, 17, 18, 20, 21, 22 under 35 U.S.C. 102 has been withdrawn in light of Applicant's amendment and arguments.

The rejection of claims 19 and 23 under 35 U.S.C. 103(a) has been withdrawn in light of Applicant's amendment and arguments.

Claims 1-11, 13, 14, 17-23 and the newly added claims 42-44 stand rejected under 35 U.S.C. 112, first paragraph, for lack of adequate written description. The new claims 42-44 are rejected insofar as they depend from the rejected claims.

Response to Arguments

In response to the rejection of claims 1-11, 13, 14, 17-23 under written description, Applicant argues (page 8, paragraph 3) that the pending claimed inventions are adequately described as filed (line 1) and that the detailed chemical structure of all the encompassed regulatory sequences, including those that hybridize with SEQ ID NO:1 under stringent conditions is known. Applicant further argues that unlike the claims at issue in *Fiers v. Revel* and *Amgen v. Chugai*, the pending claims include a structural limitation (page 9, paragraph 3, line 1), and that a skilled artisan can envision and determine the detailed chemical structure of all the possible first regulatory sequences (page 9, paragraph 2, last sentence).

These arguments have been considered but are not found persuasive for the following reasons.

The amended claims are drawn to regulatory sequences not limited to SEQ ID NO:1, which is a murine flk1 receptor sequence and/or to a human Flk-1 sequence. However, claims, as they are amended, also encompass all sequences that hybridize with SEQ ID NO:1 under stringent conditions and these sequences have not been described in sufficient detail in the specification to satisfy the written description requirement. It is not at all clear that every sequence that hybridizes with SEQ ID NO:1 has a regulatory activity and if so, that the activity would be present in endothelial cells

in vivo. Sequences that hybridize with SEQ ID NO:1 or fragments of SEQ ID NO:1, encompass vastly different structures. Further, as pointed out by the Applicant himself, human Flk-1 promoter, despite sharing important transcription factor binding sites with the mouse Flk-1 promoter is not capable of directing expression in endothelial cells *in vivo*. Therefore, it is not apparent that Applicant's disclosure adequately sets forth sufficient structure/function information to describe nucleic acids or fragments that have regulatory activity in endothelial cells *in vivo* as claimed. Further, it is not apparent that Applicant has provided even a single example of a DNA molecule or a fragment that hybridizes under stringent conditions to SEQ ID NO:1, yet is regulatory and functions to regulate expression *in vivo* in endothelial cells. Thus, not all regulatory sequences that meet the structural requirements are capable of conferring expression in endothelial cells *in vivo* and thus, all regulatory sequences encompassed by the genus "regulatory sequences" should be described in sufficient detail to meet the written description requirement.

With respect to claim 3, Applicant argues that claim 3 is directed only to mouse sequences and that the written description requirement is, therefore, met for this claim. However, claim 3, although directed to SEQ ID NO:1, also encompasses all the sequences that hybridize with it under stringent conditions, and remains rejected for the reasons described herein, above.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 1, 3, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Fixed Claim 1 (a) includes two step (i)'s and does not include a step (ii). Correction is required.

Fixed Claim 3, step (c), recites the phrase "any one of (a) to (c) capable of". It is not clear how step (c) can include itself in the step. Further, in the previous Office Action, the examiner rejected the term "capable" as being indefinite. Correction is required.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305 1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308 4242 for regular communications and (703) 308 4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-2982.

S. Pappu
April 17, 2002


REMY YUCEL, PH.D
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